

equipment. The fluid flow controls and dilution equipment require periodic recalibration. In fact, the need for recalibration illustrates the potential for inaccurate results and the undesirable operating costs that exist with many presently available hematology analyzers which use flow cytometers and/or impedance orifices. The volume of reagents required to 5 satisfy large dilution ratios increases the operating cost initially by virtue of the reagent purchase price and subsequently because of the additional waste disposal costs.

Another modern method for evaluating biologic fluid samples is one that focuses on evaluating specific subtypes of WBC's. This method utilizes a cuvette having an internal chamber about 25 microns thick with one transparent panel. A laser beam of light passing through the transparent panel scans the cuvette for WBC's. Reagents added to the sample cause each WBC to fluoresce when excited by the laser beam. The fluorescing of the particular WBC's provides an indication that particular types of WBC's are present. Because the red blood cells form a partly obscuring layer in this method, they cannot themselves be enumerated or otherwise evaluated, nor can the platelets.

There are a multitude of methods for determining the presence of soluble constituents, such as chemical components, antibodies, etc., within a sample of biologic fluid such as urine, plasma, or serum. Most of the methods require dilution of the sample and the addition of one or more reagents to the sample. Other methods require a small, but carefully metered, drop of biologic fluid sample be added to a piece of reactive film. Different analytical instruments are 10 usually required for each method of analysis, and those instruments are expensive not only in terms of initial capital cost but also in terms of the maintenance over the life of the various instruments, and the operator training necessary to properly staff the various instruments. The operator function can vary considerably from instrument to instrument, thereby increasing the complexity of the operator training and the potential for operator error. To 15 date, because of the widely differing requirements of the various tests, there is not a single instrument platform which will perform cross-discipline tests, most especially tests of

hematology, which require particle analysis, and tests of chemistry/immunochemistry or serology, which require quantitative light analysis.

What is needed is a method and an apparatus for evaluating a sample of substantially undiluted biologic fluid, one capable of providing accurate results, one that does not use a significant volume of reagent(s), one that does not require sample fluid flow during evaluation, one that can perform particulate component and chemical component analyses, and one that is cost-effective.

#### DISCLOSURE OF THE INVENTION

It is, therefore, an object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to provide analytical data for a variety of disciplines including, but not limited to, hematology, biologic chemistry, immunochemistry, serology, immunology, urinalysis, immunoassay, antibiotic sensitivity, and bacterial growth.

It is another object of the present invention to provide a single apparatus for analyzing biologic fluid samples that has the capacity to perform a greater number of tests than can be done on any single presently available device.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that uses a quiescent sample, and thereby avoids the problems associated with devices utilizing fluid flow, particularly those utilizing fluid flow outside the sample chamber and those utilizing fluid flow during the analysis process.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to search a biologic fluid sample for an optimum region to perform a given test.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to determine the volume of a given sample field in a fluid sample chamber.

According to the present invention, an apparatus for analyzing a sample of biologic fluid quiescently residing within a chamber is provided. The apparatus includes a light source, a positioner, a means for determining the volume of a sample field, and an image dissector. The light source is operable to illuminate a sample field of known, or ascertainable, area. The 5 positioner is operable to selectively change the position of one of the chamber or the light source relative to the other, thereby permitting selective illumination of all regions of the sample. The means for determining the volume of a sample field can determine the volume of a sample field illuminated by the light source. The image dissector is operable to convert an image of light passing through or emanating from the sample field into an electronic data 10 format.

An advantage of the present invention is that the present invention apparatus for analyzing a sample of biologic fluid is substantially more versatile than any presently available apparatus capable of analyzing biologic fluid. For example, the present invention has utility in numerous fields including, but not limited to, hematology, biologic chemistry, 15 immunochemistry, serology, immunology, urinalysis, immunoassays, antibiotic sensitivity, and bacterial growth. From an equipment standpoint, this versatility will give many medical offices and laboratories analytical capability that was realistically unavailable heretofore because of cost, space, manpower, training, etc. When testing a blood sample for anemia, for example, it is common to analyze the sample using hematological tests such as hemoglobin, 20 hematocrit, and reticulocyte count, and also to analyze the sample using chemical tests to establish the presence and quantity of iron or ferritin and immunochemical tests such as B-12 and folate. Using presently available devices, the medical office or laboratory would typically rely on an impedance counter or flow system to determine the hematological parameters and a chemical analyzer or immunochemistry system to determine the other analytical parameters, 25 any of which may not be readily available to the office or laboratory. The present invention apparatus, in contrast, can perform all of these tests. For those medical offices and